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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter:	SterilMed, Inc.
Contact Person:	Patrick Fleischhacker 11400 73rd Avenue North Minneapolis, MN 55369 Ph: 763-488-3400 Fax: 763-488-3350
Date Prepared:	August 13, 2001
Trade Name:	Reprocessed Endoscopic Electrodes
Classification Name and Number:	Active Electrosurgical Electrode Class II, 21 CFR 876.4300, and 21 CFR 884.4120 Panel 85
Product Code:	FAS, and HGI
Predicate Device(s):	Reprocessed endoscopic electrodes are substantially equivalent to the KSEA Vaporization Electrodes (K961702) manufactured by Karl Storz Endoscopy, and the Vaportrode Vaporization Electrodes (K890328B) manufactured by Circon/ACMI.
Device Description:	Reprocessed endoscopic electrodes are electrosurgical electrode devices that have a wide variety of tip configurations and sizes. The device is used to cut and cauterize prostate, bladder, gynecological, and urological tissue. They are used in conjunction with an endoscope and are powered by a separate RF generator. The RF generator component is not included in this submission; only the endoscopic electrodes are reprocessed.
Intended Use:	Reprocessed endoscopic electrodes are intended to be used for vaporization, ablation, coagulation and/or resection of soft tissue in the prostate and bladder as well as when ablation and coagulation are required in gynecological and urological surgical procedures.

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Functional and Safety Testing:

Representative samples of reprocessed endoscopic electrodes underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced

Conclusion:

Reprocessed endoscopic electrodes are substantially equivalent to the KSEA Vaporization Electrodes (K961702) manufactured by Karl Storz Endoscopy, and the Vaportrode Vaporization Electrodes (K890328B) manufactured by Circon/ACMI.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2002

Mr. Patrick Fleischhacker
Vice President, Regulatory
and Quality
SterilMed, Inc.
11400 73rd Avenue North
MINNEAPOLIS MN 55369

Re: K012685
Trade/Device Name: SEE ENCLOSURE 1
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulation Number: 21 CFR 884.4120
Regulation Name: Gynecologic electrocautery and accessories
Regulatory Class: II
Product Code: 78 FAS, HGI
Dated: December 6, 2001
Received: December 7, 2001

Dear Mr. Fleischhacker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for use Page

Device Name: Reprocessed Endoscopic Electrodes

Indications for Use:

Reprocessed endoscopic electrodes are intended to be used for vaporization, ablation, coagulation and/or resection of soft tissue in the prostate and bladder as well as when ablation and coagulation are required in gynecological and urological surgical procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012685